



<NOTICE>

<PREAMB>

4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0655]

Animal Generic Drug User Fee Act; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting; request for comments.

The Food and Drug Administration (FDA) is announcing the following meeting: Animal Generic Drug User Fee Act. The topic to be discussed is proposed recommendations for the reauthorization of the Animal Generic Drug User Fee Act (AGDUFA II).

Date and Time: The meeting will be held on December 18, 2012, from 1 p.m. to 4 p.m.

Location: The meeting will be held at FDA's Metro Park North Campus, 7519 Standish Pl., third floor, Meeting Room A, Rockville, MD 20855. There is parking near the building.

Contact: Jacqueline Farmer, Center for Veterinary Medicine (HFV-10), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-8695, FAX: 240-276-9744, email: AGDUFAReauthorization@fda.hhs.gov.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations, to the contact person by December 11, 2012.

If you need special accommodations due to a disability, please contact Jacqueline Farmer at least 7 days in advance.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Comments: Interested persons may submit either written comments regarding this meeting to the Division of Dockets Management (see Transcripts) or electronic comments to <http://www.regulations.gov>. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>. So that FDA can consider comments and revise the recommendations as necessary, we request that comments be submitted to the docket by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

SUPPLEMENTARY INFORMATION:

I. The AGDUFA Program

A. What is AGDUFA? What Does It Do?

FDA considers the timely review of abbreviated new animal drug applications (ANADAs) to be central to the Agency's mission to protect and promote the public health. Prior to 2009, the timeliness and predictability of the generic animal drug review program was a concern. The Animal Generic Drug User Fee Act enacted in 2008 (Public Law 110-316;

hereinafter referred to as “AGDUFA I”) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to authorize the FDA’s first-ever generic animal drug user fee program. AGDUFA I provides FDA with additional funds to enhance the performance of the generic animal drug review process. Furthermore, the authorization of AGDUFA I enabled FDA’s continued assurance that generic animal drug products are safe and effective, and enabled FDA’s continued support for lower cost alternatives to brand name drugs for consumers.

Under AGDUFA I, FDA agreed to meet review performance goals for certain submissions over 5 years from fiscal year (FY) 2009 through FY 2013. The purpose of establishing these review performance goals was to expedite the review of ANADAs and reactivations, supplemental ANADAs, and generic investigational new animal drug (JINAD) submissions and to enable FDA to speed up the application review process for generic new animal drugs without compromising the quality of the Agency's review.

B. AGDUFA Achievements

AGDUFA I established increasingly stringent review performance goals over a 5-year period from FY 2009 through FY 2013. Based on those performance goals, in the final year of AGDUFA I (FY 2013) FDA has agreed to review and act on 90 percent of the following submission types within the specified timeframes:

- Original ANADAs and reactivations within 270 days after the submission date.
- Administrative ANADAs within 100 days after the submission date.
- Manufacturing supplemental ANADAs and reactivations within 270 days after the submission date.
- JINAD study submissions within 270 days after the submission date.
- JINAD protocol submissions within 100 days after submission date.

In the 3 years of AGDUFA I review performance evaluated to date (FY 2009 to FY 2011) FDA has exceeded all performance goals for ANADAs, manufacturing supplements, JINAD data submissions, and administrative ANADAs. FDA did not meet the FY 2009 performance goal for JINAD protocol submissions, with 86 percent reviewed by the goal for that year but has exceeded the performance goal for JINAD protocol submissions in FY 2010 and FY 2011. The additional resources provided under AGDUFA I enabled FDA to completely eliminate the backlog of ANADA and JINAD submissions by August 2010.

FDA has published a number of reports that provide useful background on AGDUFA I. AGDUFA-related Federal Register notices, guidances, legislation, performance reports, and financial reports can be found at:

<http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm>.

II. Proposed AGDUFA II Recommendations

A. Enhancing the Process for Premarket Review

We are proposing to maintain the AGDUFA I goals regarding work queue procedures, timely meetings with industry, review of administrative ANADAs, review of protocols without substantial data, and amending similar applications and submissions. We are proposing the following changes to the performance goals that AGDUFA I established to further enhance the process for review of generic animal drug applications.

The Agency will review and act on 90 percent of non-administrative ANADAs within 270 days after the submission date. An application is incomplete if it would require additional data or information to enable the Agency to complete a comprehensive review of the application and reach a decision on the issue(s) presented in the application.

The Agency will review and act on 90 percent of reactivated applications:

- Within 190 days after the reactivated ANADA submission date if the Agency determines that the deficiencies are not substantial;
- Within 270 days after the reactivated ANADA submission date if the Agency determines that the deficiencies are substantial or new substantial information is provided.

The Agency will review and act on 90 percent of manufacturing supplemental ANADAs within 270 days after the submission date. A submission is incomplete if it would require additional data or information to enable the Agency to complete a comprehensive review of the submission and reach a decision on the issue(s) presented in the submission.

- If the Agency determines that the deficiencies are not substantial for manufacturing supplements requiring prior approval according to 21 CFR 514.8(b), the Agency will permit the manufacturing supplements to be resubmitted as “Supplement-Changes Being Effected in 30 Days” as described in 21 CFR 514.8(b)(3).
- If the Agency determines that the deficiencies are substantial or new substantial information is provided in the resubmission, the Agency will review and act on 90 percent of reactivated manufacturing supplements within 270 days after the resubmission date.

The Agency will review and act on 90 percent of JINAD study submissions within 270 days after the submission date. A JINAD study submission is incomplete if it would require additional data or information to enable the Agency to complete a comprehensive review of the submission and reach a decision on the issue(s) presented in the submission.

The Agency will review and act on 90 percent of resubmitted JINAD study submissions:

- Within 90 days after the JINAD study resubmission date if the Agency determines that the deficiencies are not substantial;
- Within 270 days after the JINAD study resubmission date if the Agency determines that the deficiencies are substantial or new substantial information is provided in the resubmission.

The Agency will permit comparability protocols as described in 21 CFR 514.8(b)(2)(v) to be submitted as protocols without substantial data in a JINAD file. The Agency will continue to review and act on 90 percent of JINAD submissions consisting of protocols without substantial data within 100 days after the submission date.

The Agency will develop guidance for a two-phased Chemistry, Manufacturing, and Controls technical section submission and review process under the JINAD file by the end of FY 2014.

The Agency will develop and implement a question based review process for bioequivalence submissions by the end of FY 2016. At its discretion, the Agency may extend the timeline for completion if necessary, depending on available resources.

To improve the timeliness and predictability of foreign preapproval inspections (PAIs), sponsors may voluntarily submit, at the beginning of the calendar year, a list of foreign manufacturing facilities that are included in abbreviated animal drug applications, supplemental animal drug applications, or investigational animal drug submissions and may be subject to foreign PAIs for the following fiscal year.

If such a list is voluntarily submitted, the sponsor should submit a notification 30 days prior to submitting an abbreviated animal drug application, an abbreviated supplemental animal drug application, or generic investigational animal drug submission that informs the Agency that

the application includes a foreign manufacturing facility. Should any changes to the annual list occur after its submission to the Agency, the sponsor may provide the updated information to the Agency.

B. AGDUFA II Enhancements for a Modified Inflation Adjuster and Workload Adjuster

Similar to AGDUFA I, we agreed to a fixed inflation adjuster over the 5-year period that results in the statutory revenues specified in sections 741(b) and 741(g)(3) of FD&C Act (21 U.S.C. 379j-21(b) and 379-21(g)(3)).

AGDUFA II also modifies the base years for calculating the workload adjuster, as specified in the AGDUFA II performance goals letter, to ensure that it adequately captures changes in FDA's workload during AGDUFA II.

C. Impact of AGDUFA II Enhancements on User Fee Revenue

The following table summarizes FY 2014 baseline and added funding to support AGDUFA II program, as well as the AGDUFA II total 5-year revenue:

Financial Baseline	Dollars
FY 2014 Base Revenue ¹	\$ 6,478,000
One-Time Information Technology (IT) Funding	\$ 850,000
Total Statutory Revenue for FY 2014	\$ 7,328,000
Total Financial Funding	
Total 5-Year Revenue	\$38,100,000

¹For each year in FY 2015 to FY 2018, the annual statutory revenue amounts established in section 741(b) of the FD&C Act may be further adjusted by the workload adjuster for FY 2015 to FY 2018 user fee revenues.

The total 5-year revenue for AGDUFA I was \$27,100,000. The total 5-year revenue for AGDUFA II will be \$38,100,000, which also includes one-time IT funding in the amount of \$850,000 for FY 2014.

Additionally, the fee revenue distribution has been modified from 30 percent in application fees, 35 percent in product fees, and 35 percent in sponsor fees under AGDUFA I to 25 percent in application fees, 37.5 percent in product fees, and 37.5 percent in sponsor fees under AGDUFA II. The purpose of changing the fee distribution is to increase the revenue stream stability and reduce application fee costs.

III. What Information Should You Know About the Meeting?

We will convene a public meeting to hear the public's views on the proposed recommendations for reauthorization of AGDUFA I. The public meeting will be held on December 18, 2012, at FDA's Metro Park North Campus (see Location). The meeting will include a presentation by FDA, and we will also provide an opportunity for other organizations and individuals to make presentations at the meeting or to submit written comments to the docket. So that FDA can consider comments and revise the recommendations as necessary, we request that comments be submitted to the docket by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Dated: December 3, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

<FRDOC> [FR Doc. 2012-29499 Filed 11-26-12; 4:15 pm]

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